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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,038	03/24/2000	Scott J. Wolf	7883.0004-02	2278

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/534,038	Applicant(s) WOLF ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16 and 18-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Final Rejection</u> . |

DETAILED ACTION

Response to Amendment

1. In the amendment filed 11/01/04, claims 17 & 30-42 were cancelled. Claims 15, 18, 21, 24, 26 & 29 were amended. Claims 15, 16, & 18-29 remain pending.

Response to Arguments

2. Applicant's arguments with respect to claims 15, 16, & 18-29 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

- 3 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 15, 16, 18-20, & 24-29 are finally rejected under 35 U.S.C. 102(e) as being anticipated by LaFontaine et al. (6,092,526). LaFontaine discloses a method for performing chamber-to-artery bypass between a coronary artery and a heart chamber. LaFontaine teaches that a cutting device can be used to form a lumen (i.e. channel) through heart tissue starting from the coronary artery (col. 4, lines 36-41). Since one is starting the lumen through the coronary artery, it is inherent that the device would pass first through the anterior and then through the posterior wall of the vessel and through the heart wall. LaFontaine discloses creating a lumen in the wall using an instrument such as a cutting or debulking device, boring device, rotating blade, RF ablation, laser or any other suitable mechanical or energy device (col. 4, lines 11-35). LaFontaine further teaches that a stent may be placed in the created lumen and expanded by using a catheter system (col. 5, lines 54-64). With respect to the recitation in claim 29 that the implant does not extend substantially along an axial direction of the vessel, LaFontaine shows the implant extending within the passageway offset from the vessel's axis in figures. LaFontaine et al. also discloses that the method may include delivering a drug using a suitable delivery device into the lumen formed within the wall of the heart. The substance that may be delivered includes a growth factor to enhance endothelialization in the lumen (col. 7, lines 35-53). As shown in the embodiments of figures 5B-5F, LaFontaine discloses that a stent may be placed in the created lumen and expanded by using a catheter system (col. 5, lines 54-64). Thus, the limitation of radially expansion of the implant in the passageway is met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 21-23 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over LaFontaine et al. ('526) in view of Evans et al. (5,980,548). LaFontaine et al. disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the implant or stent carry a substance for delivery to the heart wall, wherein the substance is for one of generating, stimulating, and enhancing blood vessel formation, and wherein the substance is chosen from angiogenesis factors and nucleic acid instructions for angiogenesis factors.

Evans et al. disclose inserts for deployment into the heart wall and where the inserts may be hollow, tubular members that are equivalent to a stent or implant, and the inserts can be coated with or contain growth factors, or a material that will provide vasculature or angiogenesis in the heart wall (col. 14, lines 15-20 & col. 16, lines 10-31). At the time of the invention, it would have been an obvious design choice to modify the stent of LaFontaine et al. by substituting the implant having a coating that contains growth factors or a material that will provide vasculature or angiogenesis in the heart wall as taught by Evans et al. to provide new growth of vessels and provide a lasting therapeutic effect, since substitution of parts which provide the same function would be within the level of ordinary skill in the art.

Terminal Disclaimer

5. The terminal disclaimer filed on 11/01/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates therein has been placed in the file.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571)

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272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 24th, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER